

PSJ1 Exh 5



INVENTORY CONTROL - SUSPICIOUS ORDER POLICY

Policy Number: 30-010	Version/Revision Number: 002
Effective Date: 8/1/14	Revision Date: 4/9/2015
Created Date: 8/1/14	Last Reviewed Date: 4/9/2015
Policy Owner: Matt Rogos	Department: HBC Service Co.
Reference(s): HBC-PAP001-001	

PURPOSE/OBJECTIVE:

To identify, investigate, record, and report suspicious pharmaceutical product orders

SCOPE:

This policy applies to:

- All HBC TMs who have access to the HBC pharmacy room.

POLICY:

- Identified individuals from Giant Eagle Sourcing, Pharmacy Compliance, and HBC Team Members (TMs) must review pharmacy customer orders and order trends on a regular and for - cause basis to identify suspicious drug orders
- Suspicious orders are blocked and reported to the appropriate regulatory authority within the specified time frame as required
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PROCEDURES:

Reporting suspicious prescription product orders

- Giant Eagle and HBC team members review customer orders and order history trends to identify suspicious drug orders
- Suspicious order criteria include, but are not limited to:
 - Purchases over a defined time period that exceed a pre-determined threshold
 - Orders of unusual quantities compared to a customer's order history
 - Unique pattern of orders that differs from similar customers
 - Orders received outside of the normal pharmacy customer ordering process
- identified orders are investigated to determine if the order is suspicious or legitimate
- Legitimate orders are released for processing and delivery to the customer



- Suspicious orders are blocked and reported to the applicable regulatory authorities within the specified time frame as required
 - Board of Pharmacy and FDA within three (3) business days
 - DEA (if controlled substance) upon determination
- HBC prepares and communicates any history of suspicious orders to the GE Pharmacy team as requested.
- HBC retains the records of the investigation and outcome for six (6) years

COMPLIANCE:

Non-compliance with this policy will result in progressive discipline up to and including termination in compliance with Human Resource guidelines



INVENTORY CONTROL - SUSPICIOUS ORDER POLICY

Policy Number: 30-010	Version/Revision Number: 003
Effective Date: 8/1/14	Revision Date: 4/9/2015, 02-26-2016
Created Date: 8/1/14	Last Reviewed Date: 02-26-2016
Policy Owner: GERXDC	Department: GERXDC Service Co.
Reference(s): GERXDC-PAP001-001	

PURPOSE/OBJECTIVE:

To identify, investigate, record, and report suspicious pharmaceutical product orders

SCOPE:

This policy applies to:

- All GERXDC TMs who have access to the GERXDC facility.

POLICY:

- Identified individuals from Giant Eagle Sourcing, Pharmacy Compliance, and GERXDC Team Members (TMs) must review pharmacy customer orders and order trends on a regular and for-cause basis to identify suspicious drug orders
- Suspicious orders are blocked and reported to the appropriate regulatory authority within the specified time frame as required

PROCEDURES:

Reporting suspicious prescription product orders

- Giant Eagle and GERXDC team members review customer orders and order history trends to identify suspicious drug orders
- Suspicious order criteria include, but are not limited to:
 - Purchases over a defined time period that exceed a pre-determined threshold
 - Orders of unusual quantities compared to a customer's order history
 - Unique pattern of orders that differs from similar customers
 - Orders received outside of the normal pharmacy customer ordering process
- Identified orders are investigated to determine if the order is suspicious or legitimate
- Legitimate orders are released for processing and delivery to the customer

- Suspicious orders are blocked and reported to the applicable regulatory authorities within the specified time frame as required
 - Board of Pharmacy and FDA within three (3) business days
 - DEA (if controlled substance) upon determination
- GERXDC prepares and communicates any history of suspicious orders to the GE Pharmacy team as requested.
- GERXDC retains the records of the investigation and outcome for six (6) years

COMPLIANCE:

Non-compliance with this policy will result in progressive discipline up to and including termination in compliance with Human Resource guidelines



ORDER MONITORING SYSTEM POLICY

Policy Number:	Version/Revision Number: 1
Effective Date: 02-02-2017	Revision Date:
Created Date: 02-02-2017	Last Reviewed Date:
Policy Owner: Pharmacy Policy & Procedure Group	Department: Pharmacy Operations, Pharmacy Merchandising,
Reference(s):	

PURPOSE/OBJECTIVE:

To monitor, identify, and investigate controlled substance orders exceeding system limits; then make the determination to allow the order to continue or to hold the order and report it as being suspicious as required by law.

SCOPE:

This procedure applies to the Giant Eagle Order Monitoring System team which consists of members of Pharmacy Administration, Pharmacy Operations, Pharmacy Compliance, Pharmacy Merchandising, Pharmacy Technology, Giant Eagle Rx Distribution Center teams, and Loss Prevention.

POLICY:

The Order Monitoring System (OMS) team monitors pharmacy orders to prevent possible diversion of controlled substances.

PROCEDURE:

- Controlled substances are supplied to Giant Eagle Pharmacies from three sources to include: McKesson, ANDA, and the Giant Eagle Rx Distribution Center.
- Schedule II controlled substance orders are generated using the Controlled Substance Ordering System (CSOS).
- The OMS uses algorithms to identify controlled substance orders that require investigation and documentation before releasing the order for distribution.
 - The OMS algorithm generates limits at the chemical family level based on monthly thresholds and ordering characteristics specific to the following:
 - Pharmacy location
 - Chemical
 - Generic Product Indicator (GPI)
 - National Drug Code (NDC)
 - Ordering Patterns
- In the event that an item or items in a submitted order would exceed the threshold the items are blocked and Threshold Review process is initiated
 - The Threshold Review Process has 4 potential levels of review
 - The Signer Level Review Process includes the following:
 - Review the order
 - Block the item or items exceeding threshold
 - Log the order in the OMS Investigation Log
 - The Analyst Level Review Process includes a series of standardized statistical analyses on the item(s) which may include but not be limited to the following:

- ordering history review
- prescription dispensing examination
- narcotic audit analysis
- current on hand inventory checks
 - If the store passes all parameters then the analyst can approve an increase equal to two standard deviations above the average of the last 12 months
 - If it does not pass all parameters or the submitted order would still exceed the projected increase then the analyst will escalate to The Approver Level
- The Approver Level Review Process includes notification that a store exceeded its threshold and it did not pass all of the parameters at the Analyst Level
 - The Approver reviews that analysis from the previous level and requests additional evaluative steps. These would include but not be limited to:
 - Geographical Prescription Provider Mapping
 - Geographical Prescription Patient Mapping
 - Pharmacy District Leader Consultation
 - Store Threshold Increase Request Form
 - Payment Type analysis (Cash vs. Managed Care)
 - Historic Physical Inventory Evaluation
 - Capital Returns Review
 - The Approver will have the option to approve, deny, or escalate to the Investigator Level
- The Investigator Level Review Process includes notification that a store reached its threshold and failed at least one Analyst Level parameter and based on the approver level review there is a potential security risk
 - A meeting is held between the Approver and the Investigator in addition to any requested personnel
 - An action plan is designed which may include but not be limited to the following:
 - Physical prescription review
 - Personnel Interviews
 - Store covert investigation
 - Results of the investigation will determine DEA notification
- The documentation of the review and investigation process must be retained in readily retrievable form according to the Giant Eagle Document Retention Policy and not less than two years
- The Order Management System and processes will be reviewed on a quarterly basis by the OMS Review Committee.
- The OMS Review Committee will evaluate the effectiveness of the OMS in identifying orders of unusual size, pattern, or frequency.
- The Committee will make appropriate recommendations to improve the function and efficacy of the system.
- OMS Review Committee consists of the following team members:
 - Pharmacy Administration
 - Pharmacy Operations

- Pharmacy Compliance
- Pharmacy Merchandising
- Pharmacy Technology
- Legal Counsel (as appropriate)



Giant Eagle Suspicious Order Monitoring

PURPOSE/OBJECTIVE:

To monitor, identify, and investigate controlled substance order monitoring system flags; then make the determination to allow the order to continue or to hold the order and report it as being suspicious as required by law.

SCOPE:

This procedure applies to the Giant Eagle Order Monitoring System team which consists of members of Pharmacy Operations, Pharmacy Procurement, and the Giant Eagle Rx Distribution Center teams.

PROCEDURE:

The Giant Eagle Suspicious Order Monitoring program is designed to include monitoring of all controlled substances (CII – CV) purchased by individual pharmacies based on the following criteria:

- Order Quantity
- Order Frequency
- Order Pattern

The ordering monitor system is automated and uses a set of algorithms to identify controlled substance orders that require investigation to determine if an order is to be considered suspicious.

The order monitoring system generates flags based on, but not limited to, quantity of product ordered and characteristics specific to pharmacy location, chemical, Generic Product Identifier, NDC number, and order patterns.

The investigative process if an order is flagged can include a review of the following:

- Store Purchasing patterns of controlled substances
- Store Dispensing patterns
 - Percentage of controlled substance prescriptions dispensed
- Form of prescription payment
 - Third party
 - Cash
- individual prescriptions for controlled substances
- Prescriber histories and patterns
- Interviews with store pharmacists and technicians
- Interviews with the Pharmacy District Leader

If the order is deemed suspicious:

- The DEA resident office is notified in writing



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If the order is deemed suspicious:

- The flagged item is blocked for distribution to the individual pharmacy
- The DEA resident office is notified in writing within one business day of the determination

If the order is determined not to be suspicious:

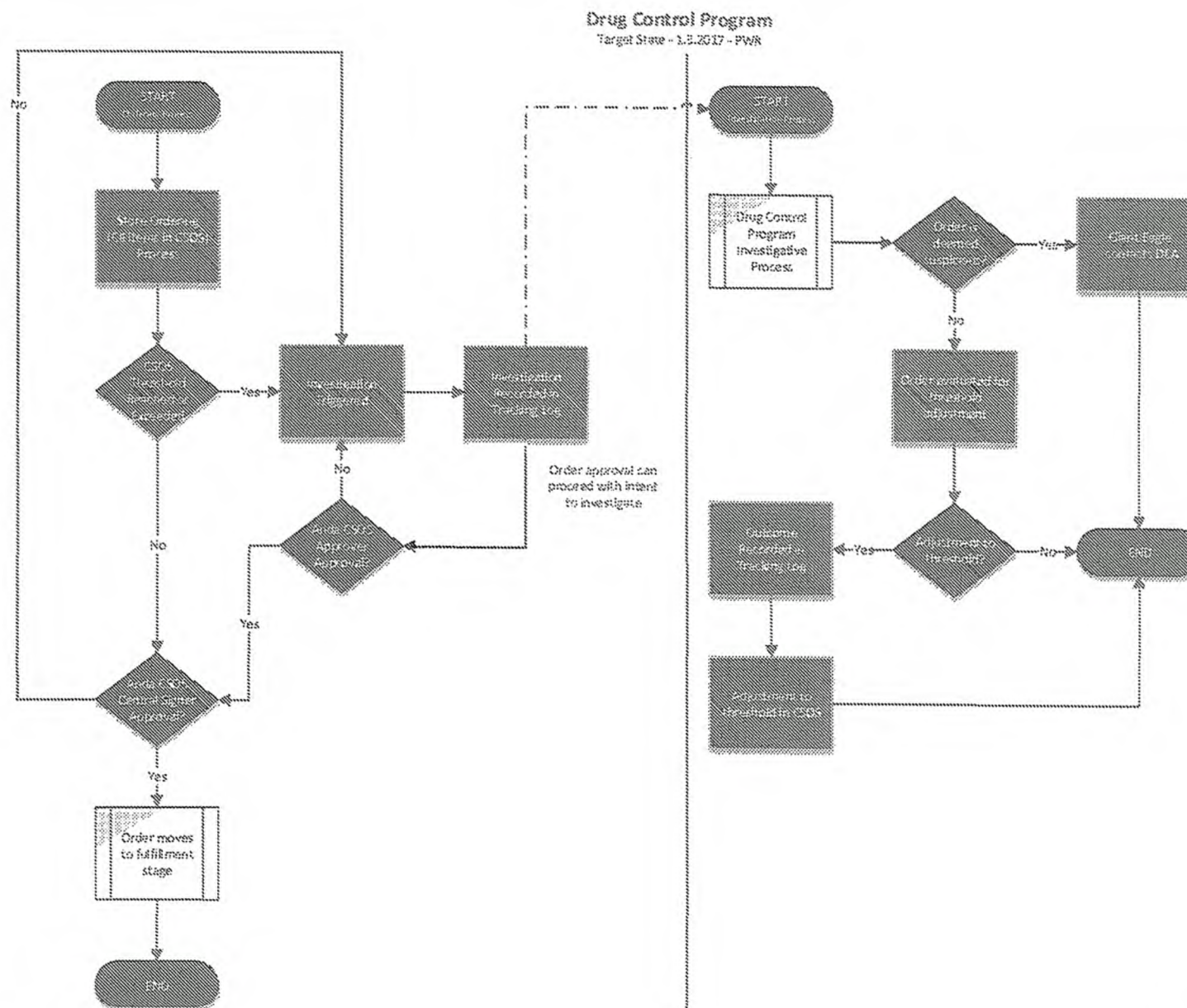
- The block is removed from the individual item
- The order is sent for fulfillment and distribution

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